

Appl. No. 09/926,001  
Amendment dated: May 12, 2004  
Reply to OA of: January 27, 2004

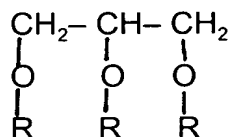
This listing of claims will replace all prior versions and listings of claims in the application.

**Listing of Claims:**

Claims 1-10(canceled).

11(currently amended). A Tuberculosis (TB) vaccine composition comprising, as adjuvant, one or more substances selected from the group consisting of:

a) monoglyceride preparations having at least 80% monoglyceride content and having a formula



wherein R is H or an acyl group containing from 6 to 24 carbon atoms with the proviso that two of the R groups are H, and

b) a fatty acid with 6 to 24 carbon atoms; and

as immunizing component, inactivated ~~Mycobacterium tuberculosis~~ Mycobacterium tuberculosis bacteria.

12(currently amended). The TB vaccine composition according to claim 11, wherein the ~~M. tuberculosis~~ M. tuberculosis bacteria are heat or formalin killed.

Appl. No. 09/926,001  
Amendment dated: May 12, 2004  
Reply to OA of: January 27, 2004

13(previously presented). The TB vaccine composition according to claim 11, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90%, and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms.

14(previously presented). The TB vaccine composition according to claim 11, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms.

15(previously presented). The TB vaccine composition according to claim 11, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

16(currently amended). The TB vaccine composition according to claim 11, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunizing component is heat-killed ~~M. tuberculosis~~ M. tuberculosis bacteria.

17(previously presented). The TB vaccine composition according to claim 15, wherein the adjuvant further comprises soybean oil.

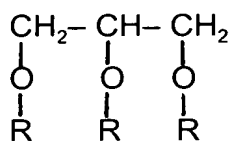
18(previously presented). The TB vaccine composition according to claim 11, wherein the composition is formulated into a preparation for mucosal administration.

19(previously presented). The TB vaccine composition according to claim 18, wherein the mucosal administration is nasal, pulmonary, oral or vaginal administration.

Appl. No. 09/926,001  
Amendment dated: May 12, 2004  
Reply to OA of: January 27, 2004

20(currently amended). An aerosol or spray package comprising a TB vaccine composition comprising, as adjuvant, one or more substances selected from the group consisting of:

a) monoglyceride preparations having at least 80% monoglyceride content and having the formula



wherein R is H or an acyl group containing from 6 to 24 carbon atoms with the proviso that two of the R groups are H, and

b) a fatty acid with 6 to 24 carbon atoms, and

as immunizing component, inactivated ~~Mycobacterium tuberculosis~~ Mycobacterium tuberculosis bacteria.

21(currently amended). An aerosol or spray package according to claim 20, wherein the ~~M. tuberculosis~~ M. tuberculosis bacteria are heat or formalin killed.

22(previously presented). An aerosol or spray package according to claim 20, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90%, acyl chains of the monoglyceride in the monoglyceride preparation and contains 8 to 20 carbon atoms.

23(previously presented). An aerosol or spray package according to claim 20, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation

Appl. No. 09/926,001  
Amendment dated: May 12, 2004  
Reply to OA of: January 27, 2004

of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms.

24(previously presented). An aerosol or spray package according to claim 20, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier oases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

25(currently amended). An aerosol or spray package according to claim 20, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunizing component is heat-killed ~~M. tuberculosis~~ M. tuberculosis bacteria.

26(previously presented). An aerosol or spray package according to claim 20, wherein the composition is formulated into a preparation for mucosal administration.

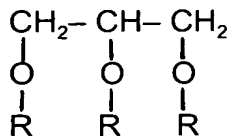
27(previously presented). An aerosol or spray package according to claim 26, wherein the mucosal administration is nasal, pulmonary, oral or vaginal administration.

28(currently amended). An aerosol or spray ~~Package~~ package according to claim 25, wherein the adjuvant further comprises soybean oil.

29(currently amended). A nose-drop package comprising a TB vaccine composition comprising, as adjuvant, one or more substances selected from the group consisting of:

a) monoglyceride preparations having at least 80% monoglyceride content and having the general formula

Appl. No. 09/926,001  
Amendment dated: May 12, 2004  
Reply to OA of: January 27, 2004



wherein R is H or an acyl group containing from 6 to 24 carbon atoms with the proviso that two of the R groups are H, and

b) a fatty acid with 6 to 24 carbon atoms; and  
as immunizing component, inactivated ~~Mycobacterium tuberculosis~~ Mycobacterium tuberculosis bacteria.

30(New) The nose-drop package, according to claim 29, wherein the M. tuberculosis bacteria are heat or formalin killed.

31(previously presented). The nose-drop package according to claim 29, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms.

32(previously presented). The nose-drop package according to claim 29, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms.

33(New) The nose-drop package according to claim 29, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic

Appl. No. 09/926,001  
Amendment dated: May 12, 2004  
Reply to OA of: January 27, 2004

agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

34(currently amended). The nose-drop package according to claim 29, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunizing component is heat-killed ~~M. tuberculosis~~ M. tuberculosis bacteria.

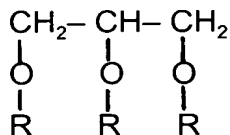
35(previously presented). The nose-drop package according to claim 29, wherein the composition is formulated into a preparation for mucosal administration.

36(previously presented). The nose-drop package according to claim 35, wherein the mucosal administration is nasal, pulmonary, oral or vaginal administration.

37(previously presented). The nose-drop package according to claim 34, wherein the adjuvant further comprises soybean oil.

38(currently amended). A method of vaccinating a mammal against Tuberculosis (TB) which comprises mucosal administration to the mammal of a protection-inducing amount of a TB vaccine composition comprising, as adjuvant one or more substances selected from the group consisting of:

a) monoglyceride preparations having at least 80% monoglyceride content and having the general formula



Appl. No. 09/926,001  
Amendment dated: May 12, 2004  
Reply to OA of: January 27, 2004

wherein R is H or an acyl group containing from 6 to 24 carbon atoms with the proviso that two of the R groups are H; and

b) a fatty acid with 6 to 24 carbon atoms; and

as immunizing component, inactivated ~~Mycobacterium tuberculosis~~ Mycobacterium tuberculosis bacteria.

39(currently amended). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 38, wherein the ~~M. tuberculosis~~ M. tuberculosis bacteria are heat or formalin killed.

40(previously presented). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 38, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms.

41(previously presented). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 38, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms.

42(previously presented). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 38, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, Physiological saline solutions, preservatives, osmotic pressure pH-controlling agents, carrier gases, PH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

Appl. No. 09/926,001

Amendment dated: May 12, 2004

Reply to OA of: January 27, 2004

43(currently amended). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 38, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunizing component is heat-killed ~~M. tuberculosis~~ M. tuberculosis bacteria.

44(previously presented). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 38, wherein the composition is formulated into a preparation for mucosal administration.

45(previously presented). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 44, wherein the mucosal administration is nasal, pulmonary, oral or vaginal administration.

46(previously presented). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 42, wherein the adjuvant further comprises soybean oil.